510(k) Summary

DEC 1 3 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k120936

Company / Contact Person

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Date Prepared

March 23, 2012

Regulatory Declarations

Common / Usual Name	TDM Multiconstituent Calibrator QMS® TDM Multi-Constituent Calibrator
Trade / Proprietary Name	Abbott TDM Multiconstituent Calibrator Thermo Scientific QMS® TDM Multi-Constituent Calibrator
Classification Regulation	21 CFR 862.3200
Device Class	Class II
Device Regulation Panel	Toxicology
Product Code	DKB

Intended Use

TDM Multiconstituent Calibrator

For in vitro diagnostic use in the calibration of the Amikacin, Carbamazepine, Digoxin, Gentamicin, Phenobarbital, Phenytoin, Quinidine, Theophylline, Valproic Acid, and Vancomycin human serum and plasma assays on the ARCHITECT *c*Systems.

Lot-specific calibrator for the ARCHITECT *c*Systems are listed in the TDM MCC Value Sheet, packaged with the calibrator.

QMS® Multi-Constituent Calibrator

For in vitro diagnostic use in the calibration of assays for the detection of Amikacin, Carbamazepine, Digoxin, Gentamicin, Phenobarbital, Phenytoin, Quinidine, Theophylline, Valproic Acid, and Vancomycin in human serum and plasma for use on clinical laboratory analyzers.

Lot-specific calibrator values with specific analyzers are provided in the value sheet packaged with the calibrator.

Legally Marketed Device to Which Equivalency is Claimed

The TDM Multiconstituent Calibrator set and QMS® TDM Multi-Constituent Calibrator set are substantially equivalent to the previously cleared CEDIA TDM Core Multi-Cals (K961659).

Device Description

Each TDM Multiconstituent Calibrator set and QMS® TDM Multi-Constituent Calibrator set is packaged in a rectangular cardboard box with a 12-bottle divider, a product insert, and a value sheet. Kits are stored refrigerated at 2-8°C.

Each kit contains 6 levels of calibrators with the following configurations.

Description	Size
Level 1	2 x 5 mL
Level 2	1 x 5 mL
Level 3	1 x 5 mL
Level 4	1 x 5 mL
Level 5	1 x 5 mL
Level 6	1 x 5 mL

The TDM Multiconstituent Calibrator set and QMS® TDM Multi-Constituent Calibrator set are prepared from a bovine serum matrix and contains the following analytes: amikacin, carbamazepine, digoxin, gentamicin, phenobarbital, phenytoin, quinidine, theophylline, valproic acid, and vancomycin. Sodium azide at 0.09% and ProClin 300 at 0.1% are present as preservatives.

The analytes and targets are listed below.

Analyte	Target						Unit
	L1	L2	L3	L4	L5	L6	
Amikacin	0.0	3.0	10.0	20.0	35.0	50.0	µg/mL
Carbamazepine	0.0	2.0	4.0	8.0	12.0	20.0	µg/mL
Digoxin	0.0	0.5	1.0	2.0	3.0	5.0	µg/mL
Gentamicin	0.0	0.5	1.5	3.0	6.0	10.0	µg/mL
Phenobarbital	0.0	5.0	10.0	20.0	40.0	80.0	µg/mL
Phenytoin	0.0	2.5	5.0	10.0	20.0	40.0	µg/mL
Quinidine	0.0	0.5	1.0	2.0	4.0	8.0	µg/mL
Theophylline	0.0	2.5	5.0	10.0	20.0	40.0	µg/mL
Valproic Acid	0.0	12.5	25.0	50.0	100.0	150.0	µg/mL
Vancomycin	0.0	5.0	10.0	25.0	50.0	100.0	µg/mL

TDM Multiconstituent Calibrator and QMS® TDM Multi-Constituent Calibrator levels are provided in liquid ready to use form and to be stored at 2-8°C until the expiration date on the label. Once opened, the opened bottles are stable for 60 days when capped tightly and stored at 2-8°C.

Summary of Testing

Evaluation Parameter	Design Input	Acceptance Criteria	Pass / Fail
Target Achievement	The concentration of pilots meet design input targets	L1: Negative L2: Difference within +/-0.3 µg/mL (Amikacin) +/-0.5 µg/mL (Carbamazepine) +/-0.1 ng/mL (Digoxin) +/-0.1 µg/mL (Gentamicin) +/-1.0 µg/mL (Phenobarbital) +/-0.6 µg/mL (Phenytoin) +/-0.2 µg/mL (Quinidine) +/-0.6 µg/mL (Theophylline) +/-3.0 µg/mL (Valproic Acid) +/-0.5 µg/mL (Vancomycin) L3: Difference within +/-15% (Digoxin) +/-10% (all other analytes) L4 to L6: Difference within+/- 10% (All analytes)	Pass
Antimicrobial Effectiveness Test (USP Category 4)	Result be "NI" per Pacifica BioLabs SOP #13B-10, Rev. 7D00	Pass challenge against: *P. aeruginosa* *E. coli* *S. aureus* *C. albicans* *A. niger*	Pass
Open Bottle Stability	60 days @2-8°C	L1: Negative L2 to L6: Value change within +/-10%	Pass
Accelerated Stress Stability to Predict Shelf Life	>=12 months @2-8°C	L1: Negative L2 to L6: Value change within +/-10%	Predicted (24 months @2-8°C)
Real-Time Stability	>=12 months @2-8°C	L1: Negative L2: Value change within +/-15% L3 to L6: Value change within +/-10%	In process

Comparison of Technological Characteristics

Comparison	Proposed Device	Predicate 1
Proprietary Name	TDM Multiconstituent Calibrator	CEDIA TDM Core Multi-Cals
Intended Use	For in vitro diagnostic use in the calibration of the Amikacin, Carbamazepine, Digoxin, Gentamicin, Phenobarbital, Phenytoin, Quinidine, Theophylline, Valproic Acid, and Vancomycin human serum and plasma assays on the ARCHITECT *c*Systems. Lot-specific calibrator for the ARCHITECT *c*Systems are listed in the TDM MCC Value Sheet, packaged with the calibrator.	The CEDIA Core TDM Multi-Cals are used to calibrate the CEDIA assays for carbamazepine, phenobarbital, phenytoin, theophylline, and valproic acid in human serum and plasma.
Analytes	Amikacin Carbamazepine Digoxin Gentamicin Phenobarbital Phenytoin Quinidine Theophylline Valproic Acid Vancomycin	Carbamazepine Phenobarbital Phenytoin Theophylline Valproic Acid
510k Number	TBD	K961659
Current Manufacturer	Microgenics	Microgenics
Classification Regulation	862.3200	862.1150
Device Class	II	II
Device Regulation Panel	Toxicology	Toxicology
Product Code(s)	DKB	JIX

Conclusion

Substantial equivalence of the TDM Multiconstituent Calibrator set and QMS® TDM Multi-Constituent Calibrator set to the previously cleared CEDIA TDM Core Multi-Cals (K961659) has been demonstrated through performance testing (Section 18) to verify that the device functions as intended and design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 13, 2012

Microgenics Corporation
Thermo Fisher Scientific
Clinical Diagnostics Division
c/o Karen Lee
46360 Fremont Blvd.
Fremont, CA 94538

Re: k120936
Trade Name: Abbott TDM Multiconstituent Calibrator; Thermo Scientific QMS® TDM Multi-Constituent Calibrator
Regulation Number: 21 CFR §862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: Class II
Product Codes: DKB
Dated: November 30, 2012
Received: December 4, 2012

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)
k120936

Device Name
Abbott TDM Multiconstituent Calibrator
Thermo Scientific QMS® Multi-Constituent Calibrator

Indications For Use

Abbott TDM Multiconstituent Calibrator

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Lot-specific calibrator for the ARCHITECT *c*Systems are listed in the TDM MCC Value Sheet, packaged with the calibrator.

Thermo Scientific QMS® Multi-Constituent Calibrator

For in vitro diagnostic use in the calibration of assays for the detection of Amikacin, Carbamazepine, Digoxin, Gentamicin, Phenobarbital, Phenytoin, Quinidine, Theophylline, Valproic Acid, and Vancomycin in human serum and plasma for use on clinical laboratory analyzers.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K120936